

From: Barry Cadden
Sent: Thursday, August 23, 2012 10:15 AM
To: Chris Keough
Subject: RE: REK solution

WE DO NOT HAVE TESTING FOR THAT PARTICULAR LOT#, BUT DO HAVE TESTING FOR EACH LOT CONNECTED TO EACH ORDER SINCE THEN.

From: Chris Keough
Sent: Thursday, August 23, 2012 8:11 AM
To: Robert Ronzio
Cc: Barry Cadden
Subject: RE: REK solution

I'm forwarding/ccing this to Barry as requested but wanted to keep you in the loop b/c it has changed – she didn't think there was an issue but has since learned otherwise.

Apparently there was an issue on this. However she (the dop) doesn't think that it's us. Their safety and compliance is looking into this because they have to do their due diligence b/c an infection occurred. DOP reassured me they don't think it's us as they have got hundreds of bags and have not had an issue. I called and was going to try and get lot # etc to "make the process easier on the lab" but before I could even ask that she explained the whole situation and that the lot is no longer in house and they only have the invoice to trace it back.

What Happened:

3 surgeries were done on the same day by the same doctor in the same room. 2 of these patients had an infection in their knee before they ever left the hospital. All 3 patients had used our Ropivacaine-Epinephrine-Ketorolac block. They just need to check everything in the process to hopefully find out what caused the infection.

I explained already how the testing works on the custom products and we may not have it for this specific lot as they are randomly checked. She fully understand and does not suspect us and brought up a couple of times how they have done hundreds of bags with no issues.

From: Chris Keough
Sent: Thursday, August 23, 2012 7:27 AM
To: Robert Ronzio
Subject: FW: REK solution

How do I find out if there is testing for this particular lot?

From: Jacqueline Califano Piccirilli [<mailto:JCalifanoPiccirilli@ghs.org>]
Sent: Wednesday, August 22, 2012 2:58 PM
To: Chris Keough
Subject: RE: REK solution

Chris,

Could you please send me the sterility test results for the product batch that was sent to us on 6/28/12 invoice # 220540?

Thanks,
Jacqui

Jacqueline Califano-Piccirilli, PharmD
Pharmacy Manager/PIC

Patewood Medical Campus
175 Patewood Drive . Greenville, SC . 29615
864-797-0080 / jcalifanopiccirilli@ghs.org

From: Chris Keough [<mailto:ckeough@medicalsalesmgmt.com>]
Sent: Wednesday, August 22, 2012 12:07 AM
To: Jacqueline Califano Piccirilli
Subject: RE: REK solution

I forgot to attach this as well!

From: Chris Keough
Sent: Tuesday, August 21, 2012 10:45 PM
To: 'Jacqueline Califano Piccirilli'
Subject: RE: REK solution

Hi Jacqui,

I spoke to my boss and his reply to your request is below.

We have run random sterility test on this product in past to test the "process" but we have recently changed some testing protocols and every lot of this type of product will be sterility tested from now on. In past small volume, special order products were randomly tested but will now be tested every time it's produced.

Each lot has a specific lot# that can be tracked to every facility + unit of use connected to that lot#. We can also track every specific ingredient used to produce a specific lot to every dosage form connected to that particular lot#. We have a full recall process that can be quickly instituted if there was ever a problem with any ingredient or final dosage form. We would contact the facility as soon as we knew about any reason for a recall.

I found out the reason for the Clonidine in the block as well: it's a post surgical injection to prophylactically prevent post-op chronic neuropathic pain due to nerve regeneration after they cut them during surgery.

I've priced out Naloxone in the past for Sam. For 1mL in a 3mL syringe Naloxone 0.4mg/mL at \$10 per syringe and this has 90 days from the date of compounding at room temperature.

I'm checking on the Sodium Bicarbonate still because as a syringe from us it has 45 days from the date of compounding in a syringe and when we had it as a vial it was 180 days from the date of compounding. I'll let you know on this on my pricing email to follow.

Thanks again Jacqui -- you should be seeing another email in the next day or two for pricing!

Chris

From: Jacqueline Califano Piccirilli [<mailto:JCalifanoPiccirilli@ghs.org>]
Sent: Tuesday, August 21, 2012 12:17 PM
To: Chris Keough
Subject: REK solution

Chris,

I need to find out if there is any batch testing on the REK solution. How do you track what batch or lot you send to us? There is nothing on the invoice that indicates what lot number or expiration of the bags sent. If there were to be a recall

on any of the ingredients, how would we be notified if one of the compounded ingredients was used in the bags in order to pull it from our shelves?

Jacqui

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